AUG 2 9 2005

K05 0269

510(k) Summary of Safety and Effectiveness

Submitted By: United Orthopedic Corporation
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Date October 6th, 2004

Contact person Gene Huang / Regulatory Affairs

Device Name: U1 Hip system - Bipolar

Common Name: Bipolar endoprosthesis

Classification Name and Reference: 21CFR 888.3390 Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented.

Predicate Device: Whiteside Biomechanics Inc- Bipolar femoral head (K981238)

Device Description:

The U1 Hip system – Bipolar is designated as a hemiarthroplasty component and is to be used with United U1 hip stem (K994078) and U2 hip stem (K003237) of total hip replacement. It is a modular type of product system. The U1 Hip system - Bipolar has 23 sizes (40-62 mm in 1 mm increments) of option with a hemispherical design, easy snap-in and take out mechanism. The metallic outer shell is produced from casting Co-Cr-Mo alloy (ASTM F75). The plastic liner with a 26 mm inner diameter is machined from extruded UHMWPE bars (ISO 5834/1). The U1 26 mm femoral head (K994078) has four different neck lengths (+0, +3, +6, +9 mm), which can meet the various needs of patient. The inner femoral head will be pressed into the polyethylene liner firstly, and then the polyethylene liner with inner head will be pressed into the outer shell using a bipolar head assembly device in the operating room.

Intended Use:

The U1 Hip system - Bipolar is indicated in partial hip arthroplasty for reduction or

relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
3. Correction of function deformity;
4. Revision procedure where other treatments or devices have failed; and
5. Treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Performance:

The U1 Hip system- Bipolar is similar to currently marketed bipolar systems. The maximum range of motion between the inner bearing liner and the hip stem exceeds 60 degrees in flexion. In addition, positive eccentricity design allows optimal transmission of load from the acetabular cup to the femoral head. A review of the mechanical test data indicated that the locking strength of this Bipolar system is strong enough to prevent locking mechanism failure in clinical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2005

Mr. Gene Huang
Manager, Regulatory Affairs
United Orthopedic Corporation
No. 57, Park Ave. 2, Science Park
Hsinchu, 300, Taiwan

Re: K050269
Trade/Device Name: U1 Hip System- Bipolar
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWY
Dated: August 4, 2005
Received: August 8, 2005

Dear Mr. Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

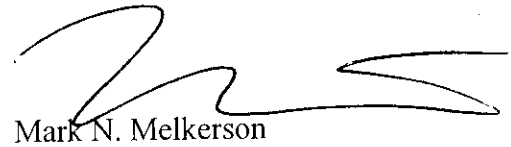
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050269

Device Name: U1 Hip system- Bipolar

Indications For Use:

This device is indicated in partial hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Correction of function deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050269